

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

OREXO AB,

Plaintiff,

v.

MYLAN PHARMACEUTICALS INC. and
MYLAN INC.,

Defendants.

Civil Action No. 3:11-cv-3788-FLW-LHG

Hon. Freda L. Wolfson, U.S.D.J.

Hon. Lois H. Goodman, U.S.M.J.

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PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW
IN SUPPORT OF MYLAN PHARMACEUTICALS INC. AND
MYLAN INC.'S MOTION TO SEAL PORTIONS OF THE JULY 6, 2012 LETTER AND
EXHIBITS TO THE JULY 8, 2012 LETTER (ECF NOS. 64 AND 65)

Arnold B. Calmann (abc@saiber.com)
Jeffrey Soos (js@saiber.com)
Katherine A. Escanlar (kae@saiber.com)
SAIBER LLC
One Gateway Center, 10th Floor
Newark, New Jersey 07102-5311
973-622-3333
973-286-2465 (facsimile)

Douglass C. Hochstetler
(DHochstetler@KelleyDrye.com)
Constantine Koutsoubas
(CKoutsoubas@KelleyDrye.com)
KELLEY DRYE & WARREN LLP
333 West Wacker Drive
26th Floor
Chicago, IL 60606
312-867-7070
312-867-7096 (facsimile)

Beth D. Jacob (BJacob@KelleyDrye.com)
Clifford Katz (CKatz@KelleyDrye.com)
Sung W. Kim (SuKim@KelleyDrye.com)
KELLEY DRYE & WARREN LLP
101 Park Avenue
Suite 1700
New York, NY 10178
212-808-7800
212-808-7897 (facsimile)

Attorneys for Defendants/Counterclaim
Plaintiffs
Mylan Pharmaceuticals Inc. and Mylan Inc.

INTRODUCTION

Pursuant to Local Civil Rule 5.3(c), Defendants Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively, "Mylan") hereby submit Proposed Findings of Fact and Conclusions of Law in support of Mylan's Motion to Seal portions of the July 6, 2012 letter and exhibits to the July 8, 2012 letter (ECF Nos. 64 and 65). Local Civil Rule 5.3(c) places the burden of proof on the moving party as to why a motion to seal or otherwise restrict public access should be granted. Specifically, it requires a showing of:

- (a) the nature of the materials or proceedings at issue;
- (b) the legitimate private or public interest which warrant the relief sought;
- (c) the clearly defined and serious injury that would result if the relief sought is not granted; and
- (d) why a less restrictive alternative to the relief sought is not available.

Mylan seeks to seal the following portions of the July 6, 2012 letter and exhibits to the July 8, 2012 letter:

July 6, 2012 Letter

- Page 4, last paragraph, line 3;
- Page 5, lines 6-7;
- Attachment to July 6, 2012 letter, Table of Disputed Terms, Rows 2-7, Column 2, all constructions except "Treatment" and "Effective amount of at least one pharmaceutically active agent in the form of microparticles adhered to the surfaces of carrier particles";

Exhibit B to the July 8, 2012 letter

- Page 2, Attachment 2, Row 3, Column 2, lines 1-5;
- Page 3, Attachment 2, Row 2, Column 2, lines 22-23;
- Page 6, Attachment 3, Row 3, Column 2, lines 5-22;
- Page 7, Attachment 3, Row 2, all of Column 2;

- Page 8, Attachment 3, Row 2, Column 2, lines 1-7, 9-15;
- Page 28, Attachment 3, Row 2, Column 2, line 27;
- Page 29, Attachment 3, Row 2, all of Column 2;
- Page 30, Attachment 3, Row 2, Column 2, lines 1-17;

Exhibit D1 to the July 8, 2012 letter

- Table, all constructions except “treatment” and “effective amount of at least one pharmaceutically active agent in the form of microparticles adhered to the surfaces of carrier particles”; and

Exhibit D2 to the July 8, 2012 letter

- Table, Row 3, Columns 2-5.

(collectively, the “Confidential Information”). Set forth below are the findings of fact and conclusions of law addressing each of the elements required by Local Civil Rule 5.3(c)(2).

These findings of fact and conclusions of law support the granting of Mylan’s Motion to Seal the Confidential Information identified herein:

I. The Nature of the Materials or Proceedings at Issue

A. Findings of Fact

1. The Confidential Information consists of information found in Mylan’s Abbreviated New Drug Application (“ANDA”), including information regarding the formulation and manufacture of Mylan’s ANDA product. Mylan considers this information, and treats this information as, confidential and proprietary material that includes nonpublic trade secrets.

B. Conclusions of Law

2. There exists in civil cases a common law public right of access to judicial proceedings and records. Goldstein v. Forbes (In re Cendant Corp.), 260 F.3d 183, 192 (3d Cir. 2001) (citing Littlejohn v. BIC Corp., 851 F.2d 673, 677-78 (3d Cir. 1988)). The party seeking to seal any part of a judicial record bears the burden of demonstrating that “the material is the

kind of information that courts will protect.” Miller v. Indiana Hosp., 16 F.3d 549, 551 (3d Cir. 1994) (quoting Publicker Indus., Inc. v. Cohen, 733 F.2d 1059, 1071 (3d Cir. 1984)).

3. This Court has the power to seal where confidential information may be disclosed to the public. Fed. R. Civ. P. 26(c)(1)(G) allows the court to protect materials containing “trade secret[s] or other confidential research, development, or commercial information[,]” upon motion by a party, to prevent harm to a litigant’s competitive standing in the marketplace. See Zenith Radio Corp. v. Matsushita Elec. Indus. Co., Ltd., 529 F. Supp. 866, 889-91 (E.D. Pa. 1981).

II. The Legitimate Private or Public Interest which Warrant the Relief Sought

A. Findings of Fact

4. The Confidential Information sought to be sealed contains formulation and manufacturing information regarding Mylan’s ANDA products that Mylan asserts is confidential and proprietary.

5. Mylan has an interest in not publicly disclosing this information and relies on such information to gain a competitive advantage in the pharmaceutical industry.

B. Conclusions of Law

6. Courts have recognized that the presumption of public access is not absolute and may be rebutted. Republic of the Philippines v. Westinghouse Elec. Corp., 949 F.2d 653, 662 (3d Cir. 1991). “Every court has supervisory power over its own records and files, and access has been denied where court files might have become a vehicle for improper purposes.” Littlejohn, 851 F.2d at 678 (quoting Nixon v. Warner Commc’ns, Inc., 435 U.S. 589, 598 (1978)).

7. Courts may deny access to and seal a document when it encompasses

business information that might harm a litigant's competitive standing. See Littlejohn, 851 F.2d at 678 (citations omitted).

8. The District of New Jersey has held that the inclusion of trade secrets and other confidential information in documents warrant the sealing of such documents. "A well-settled exception to the right of access is the 'protection of a party's interest in confidential commercial information, such as a trade secret, where there is a sufficient threat of irreparable harm.'" In re Gabapentin Patent Litig., 312 F. Supp. 2d 653, 664 (D.N.J. 2004) (citation omitted). "The presence of trade secrets or other confidential information weighs against public access and, accordingly, documents containing such information may be protected from disclosure." Id. (citations omitted).

9. Information included in an ANDA often consists of trade secrets, and federal law requires ANDAs to remain confidential. See id. at 667 n.7 (citing 21 C.F.R. § 314.430(b)-(d)). As such, a party's confidential processes, chemical formulas and specifications, and research information should be sealed. Gabapentin, 312 F. Supp. 2d at 667-68.

III. Clearly Defined and Serious Injury Would Result if the Relief Sought is Not Granted

A. Findings of Fact

10. As it consists of non-public and confidential formulation and manufacturing information that is otherwise unavailable to third parties, the public disclosure of the Confidential Information found in the July 6, 2012 letter and exhibits to the July 8, 2012 letter would pose a substantial risk of harm to Mylan's legitimate proprietary interests and competitive position.

B. Conclusions of Law

11. The district court has discretion to balance the factors for and against

access to court documents. See Pansy v. Borough of Stroudsburg, 23 F.3d 772, 781 (3d Cir. 1994).

12. Protection of a party's interest in confidential commercial information, such as a trade secret, is a sufficient threat of irreparable harm, and is clearly defined as a serious injury. See Publicker, 733 F.2d at 1071.

IV. No Less Restrictive Alternative is Available

A. Findings of Fact

13. Once confidential information is disclosed to the public, it can never again be sealed or maintained as private. Moreover, Mylan's request to seal the Confidential Information is tailored to restrict access only to Mylan's confidential and proprietary formulation and manufacturing information.

14. The disclosure of this confidential, proprietary information would pose a financial and competitive risk to Mylan. Accordingly, the only way to protect Mylan's confidential interests is to seal the identified portions of the July 6, 2012 letter and exhibits to the July 8, 2012 letter.

15. Only those portions of the July 6, 2012 and exhibits to the July 8, 2012 letter from which may be discerned confidential and proprietary information will be sealed.

B. Conclusions of Law

16. The sealing of confidential documents and information is an accepted practice in the District of New Jersey. See, e.g., In re Gabapentin Patent Litig., 312 F. Supp. 2d 653 (D.N.J. 2004).

17. Under Local Civil Rule 5.3(c)(2), a party seeking to seal documents must meet the fourth prong that no less restrictive alternative to the relief sought is available. See Securimetrix, Inc. v. Iridian Techs., Inc., 2006 WL 827889, at *2 (D.N.J. Mar 30, 2006).

18. For all the above reasons, and because Mylan's interests in the Confidential Information identified herein outweigh the minimal, if any, public interest in its disclosure, there is good cause to grant the instant Motion to Seal.

Dated: July 16, 2012

Respectfully submitted,

SAIBER LLC

Attorneys for Defendants/Counterclaim
Plaintiffs
Mylan Pharmaceuticals Inc. and Mylan Inc.

s/ Arnold B. Calmann

Arnold B. Calmann (abc@saiber.com)
Jeffrey Soos (js@saiber.com)
Katherine A. Escanlar (kae@saiber.com)
One Gateway Center, 10th Floor
Newark, New Jersey 07102-5311
973-622-3333
973-286-2465 (facsimile)

Douglass C. Hochstetler
(DHochstetler@KelleyDrye.com)
Constantine Koutsoubas
(CKoutsoubas@KelleyDrye.com)
KELLEY DRYE & WARREN LLP
333 West Wacker Drive
26th Floor
Chicago, IL 60606
312-867-7070
312-867-7096 (facsimile)

Beth D. Jacob (BJacob@KelleyDrye.com)
Clifford Katz (CKatz@KelleyDrye.com)
Sung W. Kim (SuKim@KelleyDrye.com)
KELLEY DRYE & WARREN LLP
101 Park Avenue
Suite 1700
New York, NY 10178
212-808-7800
212-808-7897 (facsimile)